

**Extramural Invention Reporting Compliance Responsibilities
Electronic (Edison) and Paper Mechanisms**

ACTION	WHEN	DISCUSSION	37 CFR REFERENCE	COMPARISON PAPER VS. EDISON	NIH CONTACT
Employee Agreement to Disclose All Inventions : The agreement to be obtained by the grantee/contractor organization is that the employee will abide by the terms of the patent rights clause.	At time of employment— term of employment.	Grantee/contractor organizations must have policies in place regarding ownership of intellectual property, including conflict of interest issues.	401.14(f)(2)		Extramural Inventions & Technology Resources Branch, OPERA
Invention Report : A report of an invention that identifies inventor(s), federal agency grant or contract number, and date of any public disclosure. Date of submission establishes time frames for all future actions. Must be complete in technical detail. The term "subject invention" means any invention of a grantee or contractor organization conceived or first actually reduced to practice in the performance of work under a federal funding agreement.	Within 2 months of inventor's initial report to the grantee/contractor organization.	There is no single format for disclosure, acceptable in any form. Cover letter stating existence of invention, and written technical detail, signed by the inventor. Must be in writing, fax copy acceptable.	401.14(a)(2) 401.14(c)(1)	Notification of existence of invention done electronically, invention disclosure document (signed by inventor) accepted via fax.	Extramural Inventions & Technology Resources Branch, OPERA
Rights to Inventions on Subcontracts : Subcontractors retain rights to their subject inventions.	Same reporting responsibilities, obligations and time frames as prime grantee/ contractor organization.	Prime grantee/contractor organization cannot require ownership of subcontractor's subject invention(s).	401.14(g)(1) 401.14(g)(2)		Grants or Contracts Management Office
Election of Title to Invention : Grantee/contractor organization notifies NIH that it will retain ownership of invention and take steps to commercialize the invention.	Within 2 years of reporting to NIH. If disclosed publicly, this period is decreased.		401.14(b) 401.14(c)(2) 401.14(f)(1)	Election of title handled electronically using Edison, otherwise a signed paper document is required.	Extramural Inventions & Technology Resources Branch, OPERA
Non-election of Title to Invention : Grantee/contractor organization notifies NIH that it will not retain ownership of an invention, or grantee/contractor does not elect to retain title within 2 years from date invention is reported. Title then vests with the government.	Within 2 years of reporting to NIH. If disclosed publicly, this period is decreased.	Effectively a waiver to the government. Cognizant NIH Technology Development Coordinator may elect title on behalf of the government.	401.14(c)(2) 401.14(d)	Handled electronically through Edison, otherwise a signed document is required.	Extramural Inventions & Technology Resources Branch, OPERA
File Patent Application	Within 1 year after election of title.	Time frame may vary if invention made public.	401.14(c)(3)		File with U.S.Patent and Trademark Office
Assignment to Third Party : Grantee/contractor organization must first waive rights to the invention. NIH Office of Technology Transfer must decide whether to take title on behalf of the government, allow a third party to obtain rights, or move the invention into the public domain.	Action must be taken during the 2 year disclosure period, plus any extensions	If waiver approved, third party has 1 year to file patent and is bound by same conditions imposed on grantee/contractor organization. If	401.14(k) for non-profits. Note the distinction	Information available on Edison Home Page. Require signatures of	Extramural Inventions & Technology Resources

ACTION	WHEN	DISCUSSION	37 CFR REFERENCE	COMPARISON PAPER VS. EDISON	NIH CONTACT
Decision must be coordinated through cognizant NIH Technology Development Coordinator and OPERA. Note: Non-profits cannot assign rights without the government's permission.	in time.	not filed, government takes title. Third party responsible for keeping government informed.	between small businesses and non-profit organizations.	grantee/contractor organization and third party. At present, this cannot be done entirely electronically.	Branch, OPERA
Inventor Certification: Documentation needed when a grantee/contractor organization waives rights to the invention and the inventor is interested in pursuing the invention. The government must waive its rights before any other party can elect title. The inventor or third party has the same responsibilities as the grantee/contractor organization. Grantee/contractor organization can waive rights to the inventor directly with permission of the NIH Office of Technology Transfer, after consultation with the grantee/contractor. The inventor must actively pursue development (i.e., patent rights and commercialization) of the invention.	At the time the grantee/contractor organization elects not to pursue title and the inventor requests rights in the invention.	First, the grantee/contractor organization must elect not to retain rights in the invention. Second, the inventor must agree to all terms associated with invention reporting as detailed in 37 CFR 401 and must pursue patent and commercialize. Must be in writing, fax copy acceptable. See: http://www.iedison.gov/Edison/INVCERPR1.html	401.14(k)(1) non-profits	Status indicated using Edison; all other issues (such as outstanding documents required) should be resolved prior to proceeding further, paper receipt (via fax) of inventor certification.	OPERA assisted by: Office of Technology Transfer and Technology Development Coordinator
Issued Patent: Provide NIH with patent filing date, number, title of patent, issue date and government support clause.	At the time of issue.	Patent must include government support clause.	401.5(f)(2) 401.14(f)(4)	All data received electronically if using Edison, otherwise information required in writing.	Extramural Inventions & Technology Resources Branch, OPERA
Request for Extension of Time: For election of title, or filing a patent application.	Prior to any statutory bar.	The first extension is preapproved. Additional extensions need written approval from OPERA, with good cause shown in writing.	401.14(c)(4)	Can be requested electronically if using Edison; otherwise request must be in writing.	Extramural Inventions & Technology Resources Branch, OPERA
Discontinuance of Patent Application: Payment of Maintenance Fees, or Defense in a Reexamination or Opposition proceeding on a Patent: Must notify NIH and provide relevant information and documents (e.g., patent application or patent) such that a determination to protect government interests can be made.	At anytime in the process, but prior to established deadlines.	NIH has the option to pursue the patent application or the patent if not being properly pursued or maintained.	401.14(f)(3) 401.6	Indication may be made via Edison or through written correspondence.	Extramural Inventions & Technology Resources Branch, OPERA
Annual Utilization Report: Required for all inventions that have other than provisional patent filings or are licensed without a patent (applicable to inventions where NIH is the Primary Agency only). Report includes latest stage of development, date of first commercial sale or use, gross royalties and other income, number of licenses (small business, exclusive, non-exclusive, domestic manufacture waiver), and gross sales of any products developed from the invention .	Annually.	For grants and contracts, due October 31st. No standardized format as long as minimum required information is supplied for each invention. Data is for each federal fiscal year, October 1 through September 30 of the following year. Report license count information for all licenses in force for any part of the fiscal year, and royalties and sales information for income or sales made during that fiscal year.	401.14(h)	Can be submitted electronically using Edison, otherwise submission may be made of the same data in writing.	Extramural Inventions & Technology Resources Branch, OPERA
Annual Invention Statement (on continuation grant application; specific to grants only): Grantee organizations must certify whether a subject invention was made or reduced to practice during the previous	Part of the preaward application submission and	For grants, response to question on the face page of the PHS 2590 grant application or as a check list	401.5(f)(3)	An invention reported on a continuation application must	Grants Management Office and

**Extramural Invention Reporting Compliance Responsibilities
Electronic (Edison) and Paper Mechanisms**

ACTION	WHEN	DISCUSSION	37 CFR REFERENCE	COMPARISON PAPER VS. EDISON	NIH CONTACT
budget period. This includes non-competing continuation (PHS 2590) and competing continuation (PHS 398) applications.	review process.	item on the PHS 398 grant application. Additional details may be included in the body of the application.		ultimately be established in the Edison system. Use either hardcopy of electronic entry.	Extramural Inventions & Technology Resources Branch, OPERA
Final Invention Statement and Certification (Form HHS 568): For grants and contracts, report all subject inventions derived or reduced to practice during the performance of the grant or contract. If none, submit a negative report. Submit all reports to the awarding unit grants or contracts management office.	Due 90 days after the project ends.	Must be reconciled by grants/contracts management and OPERA with previously submitted information. Information available on Edison web site regarding HHS 568 submission.	401.5(f)(1)	At present, this final closeout form is paper-based .	Extramural Inventions & Technology Resources Branch, OPERA Grants or Contracts Management Office

Extramural Inventions and Technology Resources Branch, OPERA, NIH
6705 Rockledge Drive, Room 1140A, MSC 7750
Bethesda, MD 20892-7980
(301) 435-1986; Fax (301) 435-0272
E-mail: edison@od.nih.gov
Interagency-Edison Home Page: <http://www.iedison.gov>